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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/315,292 05/20/99 BENNETT

C ISIS-3561

EXAMINER

HM12/0118

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ART UNIT

PAPER NUMBER

1635

DATE MAILED:

01/18/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/315,292**

Applicant(s)

**BENNETT ET AL.**

Examiner

**Mark L. Shibuya**

Group Art Unit  
**1635**



☒ Responsive to communication(s) filed on Sep 15, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-63 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-36, and 62, pharmaceutical compositions, classifiable in class 536, subclass 24.5.
  - II. Claims 37-61, and 63, drawn to methods of administration of a aerosolized nucleic acid into the lungs, and a device therefor, classifiable in class 514, subclass 44.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in a materially different process of using as hybridization probes for genes.
4. Claims 1-61 are generic to a plurality of disclosed patentably distinct species comprising oligonucleotides linkages wherein at least one linkage is:
  - A1/ 3'-methylenephosphonate linkage
  - B1/ Non-phosphorus containing oligonucleoside linkage
  - C1/ 2'-5' linkage

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D1/ 3-deoxy-3-amino phosphoramidate linkage.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims 1-17, and 33-61 are generic to a plurality of disclosed patentably distinct species comprising antisense oligonucleotides that are antisense to the following:

- A2/ Gene coding for a cytokine
- B2/ Gene coding for ICAM-1
- C2/ Gene coding for ELAM-1
- D2/ Gene coding for VCAM-1
- E2/ Gene coding for B7-1
- F2/ Gene coding for B7-2
- G2/ Gene coding for CD40
- H2/ Gene coding for LFA-3
- I2/ Gene coding for PECAM-1

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- J2/ Gene coding for a *ras* oncogene
- K2/ Gene coding for a H-ras oncogene
- L2/ Gene coding for a K-ras oncogene
- M2/ Gene coding for Protein Kinase C
- N2/ A unique portion of the genome of *Mycobacterium tuberculosis*
- O2/ A unique portion of the genome of *M. bovis*
- P2/ A unique portion of the genome of *Streptococcus pneumoniae*

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Claims 62 and 63 are generic to a plurality of disclosed patentably distinct species comprising oligonucleotides linkages wherein at least one linkage is:

- A3/ ISIS-15839
- B3/ ISIS-13312
- C3/ ISIS-9605

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D3/ ISIS-9606  
E3/ ISIS-14859  
F3/ ISIS-17709  
G3/ ISIS-17044  
H3/ ISIS-28089  
I3/ ISIS-104838

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicants are required to elect a single disclosed species as set forth in paragraph 4, a single disclosed species as set forth in paragraph 5, and a single disclosed species as set forth in paragraph 6, wherein said paragraphs 4-6 are of the instant Restriction Requirement.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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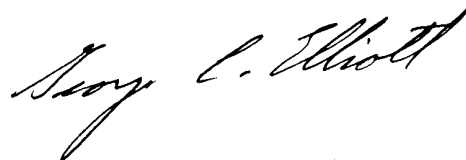
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC), J.D., Ph.D.*, whose telephone number is (703) 308-9355.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

12. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

mls  
January 8, 2000

A handwritten signature in cursive script, reading "George L. Elliott". The signature is written in dark ink and is positioned above a faint, rectangular stamp that is mostly illegible.